

## **DETAILED ACTION**

### ***Summary***

1. Receipt of Applicant's Arguments/Remarks and amended claims filed 01/07/08 is acknowledged.

It is to be noted that as of this date, no information disclosure statement is of record in this application.

The rejections made in Office action dated 03/09/07 under 35 USC 112.1 and 35 USC 112.2 have been withdrawn in view of Applicant's Amendments.

Claim 7 has been amended. Claims pending in the prosecution are claims **7-14**.

***Applicant's amendments necessitated the following new grounds of rejections.***

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recite the limitation that "the mixture comprises no organic solvent, no oil and no fat ". This limitation is confusing and contradictory because the dependent claim

Art Unit: 1612

13 requires emulsifier which comprises oil phase along with aqueous phase and dependent claim 14 requires lecithin. The claim is thus indefinite.

Claim 7 recites the limitation "less than 20 percent for surface active substance". It should be noted that less than 20 % reads on any amount which is less than 20 % such as even zero. The claim is therefore indefinite. Appropriate corrections are required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koehler et al. (US 6,500,473 B1).

Koehler et al. discloses a composition comprising coloring substance, which is dispersible and is useful for the preparation of health improving products and /or coloring products for use in the coloring of edible products including food products and nutraceuticals, and for coloring of pharmaceutical products (abstract). The coloring substance bodies have an average largest dimension of 10 micrometer (column 2, lines, 65-67). The coloring substance is a solid pigment (column 2, lines 53-54). The coloring composition include carotenoids, curcumin, carmine, porphyrin, chlorophyll, turmeric curcuma root and polyphenols (column 4 and 5, lines , 59-65 and 10-30). The coloring

substance bodies in the composition are solid particles, such as solid particles of carotenoids, carmine, curcumin and chlorophyllin 9column 6, lines 10-14). The additives as disclosed are sugar carbohydrate glucose, antioxidant and preservatives are disclosed in column 8, lines, 15-21).

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koehler et al. (US 6,500,473 B1) in view of Bunick (US PG Pub. 2003/0215585 A1).

The teachings of Koehler et al. has been discussed above. Koehler et al. does not disclose coloring agents such as riboflavin, anthocyanin and betanin. However, Bunick discloses such coloring agents in the composition. Bunick discloses an enrobed core such as a tablet core that has a coating made of one or more patterned films (abstract). The film comprises coloring agents suitable for use in pharmaceutical applications for instance, riboflavin, betanin, anthocyanin, chlorophyllin, carotenes etc. Bunick further discloses that such coatings provide visual distinctions (column 2, paragraph [0013] and discloses on page 1, paragraph [0004]) that colors have been known to provide enhanced aesthetic appeal as well as improved product identification and brand recognition by the consumers.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to utilize various coloring agents such as riboflavin, anthocyanin and betanin as disclosed by Bunick in the compositions forwarded by Koehler et al. because such coloring agents provide enhanced aesthetic appeal to the composition. Further, since Bunick discloses that such coloring agents are pharmaceutically suitable

Art Unit: 1612

and since Koehler teaches using the composition for pharmaceutical purposes, a skilled artisan would have been motivated to prepare a solid color composition by using coloring agents such as riboflavin, anthocyanin and betanin along with carotenes, carotenoids and copper chlorophyllin compounds with a reasonable expectation of success.

### ***Response to Arguments***

7. Applicant's arguments filed 01/07/08 have been fully considered but they are not persuasive.

Applicant argues that "the patent to Koehler et al. discloses a coloring substance composition. Koehler et al. do not disclose mixing a color dispersion at a temperature of 20°C to 70°C. Koehler et al. do not disclose any temperature range for producing the color dispersion. The composition of the invention, without organic solvent, oil or fat permits the mixture to be worked at the low temperature range recited in the claims. There is also no disclosure of the weight percentage of surface active substance as in the presently claimed invention."

Applicant's arguments are not persuasive because the variation in temperature is a process limitation which does not hold patentable weight in product by process claims. Applicant has not shown that the specific temperature range changes the characteristics of the product claimed. Since the product is still the same as disclosed in prior art i.e. color mixture with the claimed particle size, the claimed invention is obvious over the prior art. Examiner cites MPEP in this context:

### **2113 Product-by-Process Claims [R-1]**

#### **PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS**

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Applicant contends that no percent amount is shown for surface active agent. In response to this argument, examiner points that amounts and percentages in a composition can be varied by doing experimental manipulations. Applicant has not provided any evidence in a scientific and statistical form which shows unexpected and superior results with the specific percentage claimed in the application. Besides, independent claim 7 recites the amount to be less than 20 % with no lower limit for less than 20 % which makes the claim indefinite. The rejection is therefore maintained.

8. Claims 7-8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Runge et al. (US 6,287,615 B1.)

Runge et al. discloses the use of solubilized carotenoid preparations for coloring foods (abstract). Various carotenoids that are disclosed as food color additives are lycopene, carotene, astaxanthine, lutein beta- carotene etc. as stated (column 2, lines,

Art Unit: 1612

31-46). The carotenoids are suspended in emulsifiers either in pure form or else in the form of an oily dispersion, where the dispersant is mineral or vegetable oil and preferably lecithin (column 2, lines, 44-47 and column 3, line 16). Preservatives are disclosed in (column 3, lines, 54-57 and sugars, sucrose, glucose, fructose are disclosed in column 4, lines, 1-2). The stable solubilized carotenoid preparations for food coloring and pharmaceutical preparations have particle size in the range of 10-200 nm (column 1, lines,.46-49).

### ***Response to Arguments***

9. Applicant's arguments filed 01/07/08 have been fully considered but they are not persuasive.

Applicant argues that "Runge et al., it can be seen that this patent discloses the use of solubilized carotenoid preparations for coloring food preparations. Runge et al. do not disclose mixing a color dispersion at a temperature of 20°C to 70°C, as in the presently claimed invention. In contrast, at column 1, line 58 and column 2, line 16, Runge et al. explicitly disclose that the color dispersion is mixed at a temperature of 120°C to 200°C. Furthermore, at column 2, lines 44-46, Runge et al. teach the carotenoid mixed in an oily dispersion, which is different from the presently claimed invention which does not use oil. Additionally, Runge et al. do not disclose a surface active substance present in an amount of less than 20 weight percent."

Applicant's arguments are not persuasive because the variation in temperature is a process limitation which does not hold patentable weight in product by process claims. Applicant has not shown that the specific temperature range changes the characteristics

Art Unit: 1612

of the product claimed. Since the product is still the same as disclosed in prior art i.e. color mixture with the claimed particle size, the claimed invention is obvious over the prior art. Examiner cites MPEP in this context:

### **2113 Product-by-Process Claims [R-1]**

#### **PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS**

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Applicant contends that no percent amount is shown for surface active agent. In response to this argument, examiner points that amounts and percentages in a composition can be varied by doing experimental manipulations. Applicant has not provided any evidence in a scientific and statistical form which shows unexpected and superior results with the specific percentage claimed in the application. Besides, independent claim 7 recites the amount to be less than 20 % with no lower limit for less than 20 % which makes the claim indefinite. The rejection is therefore maintained. Regarding the argument that the claimed invention does not use oil, the examiner points out, that the dependent claim 13 claims emulsifiers and the dependent claim 14 claims lecithin which does not support the statement.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.



Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612

/Snigdha Maewall/  
Examiner, Art Unit 1612